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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/763,339  | 01/26/2004  | Shawn R. Feaster     | 034047.003DIV1 (W<br>00-23B) | 7108             |
| 53502   | 7590        | 08/31/2007           | EXAMINER                     |                  |
| OFFICE OF THE STAFF JUDGE ADVOCATE (SKS)<br>U.S. ARMY MED. RESEARCH & MATERIEL COMMAND<br>504 SCOTT STREET<br>ATTN: MCMR-JA (MS. ELIZABETH ARWINE)<br>FORT DETRICK, MD 21702-5012 |             |                      | SHEN, BIN                    |                  |
| ART UNIT  |             | PAPER NUMBER         |                              | 1657             |
| MAIL DATE   |             | DELIVERY MODE        |                              | 08/31/2007 PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                 |                |
|------------------------------|-----------------|----------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)   |
|                              | 10/763,339      | FEASTER ET AL. |
|                              | Examiner        | Art Unit       |
|                              | Bin Shen        | 1657           |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 June 2007.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 29-36 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 31-34, 36 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 29,30,35 and 39 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date.
- 5) Notice of Informal Patent Application
- 6) Other:

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This application contains claims 31-34, 36 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

In view of applicant's argument, the rejection under 35 USC § 102(b) is hereby withdrawn.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29, 30, 35, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doretti et al. (Applied Biochemistry and Biotechnology 1998;74:1-12) in view of Magnotti et al. (Clinica Chimica Acta, 1988;315:315-332), and further in view of Ellman et al. (Biochemical Pharmacology 1961;7:88-95).

Doretti et al. teach an enzyme biosensor (read as a device) for the determination of cholinesterase on polymer membrane (see abstract). The biosensor uses physical entrapment strategies (same function as a sealed chamber, see page 2, line 11-14) to co-immobilize acetylcholinesterase/choline oxidase (AChE/ChO) or butyrylcholinesterase/ChO (BchE/ChO), and it detects activities/concentrations of different substrates (read on as a

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plurality of proteins, see page 2, 7<sup>th</sup> paragraph). The sensitivity for each substrate and for each protein is determined by measuring the reaction rates at different concentrations through calculating a linear relationships (see Fig. 1, Fig. 3 and Table 1).

Doretti et al. do not teach use of a handheld device with a cartridge to detect cholinesterase.

Magnotti et al. teach the reagents (see pages 317-318) needed for the testing device and the advantages to develop a portable and convenient device/kit (read on as handheld) with stable, premixed reagents (read on as cartridge) to measure cholinesterases in a field assay (see abstract and also page 329, 3<sup>rd</sup> full paragraph) because field monitoring erythrocyte and plasma cholinesterase activities is beneficial to agricultural workers and others at risk for pesticide exposure (see page 331, 2<sup>nd</sup> full paragraph).

Ellman et al. teach a new and rapid colorimetric determination of acetylcholinesterase activity which is later developed into the Test-Mate OP kit by EQM Research Inc., Cincinnati, OH, USA (as stated on page 1078, lines 11-14 of Paz-y-Mino et al. Environmental Health Perspectives 2002;110:(1077-1080)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to develop a handheld device with a biosensor (as taught by Doretti et al.) and a cartridge (whose convenience is suggested by Magnotti et al.) to monitor enzyme activity because Doretti et al. teach a biosensor to detect enzyme activity, and Magnotti et al. teach the reagents that are needed for the enzyme assay and suggest to develop a portable and convenient device to monitor

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cholinesterases activity in the field. One would have been motivated to make the modification because Magnotti define the optimal criteria for field measurement of cholinesterase (see page 328, 1<sup>st</sup> paragraph of Discussion) and the need for a portable/handheld device/kit with stable, premixed reagents (cartridge), and would reasonably have expected success because Doretti et al. teach how to made a biosensor for cholinesterase detection, and Magnotti et al. teach many advantages of developing a portable, convenient and stable assay system to be used in the field.

The Test-Mate OP system has all the components that are required for the detection of cholinesterase as described by Ellman et al., thus it would have been obvious to one of ordinary skill in the art to use the Test-Mate OP kit to detect, measure or monitor the activities or concentrations of cholinesterase instead of the claimed device.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed 6/29/2007 have been fully considered but they are not persuasive.

Applicant argues that Doretti does not teach a test sample which comprises the protein itself plus at least one similar protein, the sensitivity coefficient of a protein is not

calculated using inhibited dilutions and uninhibited dilutions of the protein.

It is the examiner's position that Doretti teaches more than one substrates (page 2, end of 7<sup>th</sup> paragraph), and the phrase "belongs to" in claim 29, line 3 does not mean more than one proteins are presented in the test sample. "inhibited dilutions and uninhibited dilutions of the protein" can be interpreted as different dilutions of the protein/substrate which is taught by Doretti (see page 10, Fig. 3).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### **Conclusion**

No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December

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28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

*R. Gitomer*

RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200

*B Shen*

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